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In This Issue

Home Health Care Industry Threatened by New Regulations

In an era when the population is aging and more people are seeking alternatives to institutional care, home health care has provided a welcome change and created a growing industry. Medicare payments to home health care agencies have allowed more elderly and disabled Americans to enjoy this option. However, in testimony before the Senate Small Business Committee on July 15, Chief Counsel for Advocacy Jere W. Glover said that new rules issued by the Health Care Financing Administration (HCFA) will increase the cost to small firms offering home health care. According to Glover, the controversy surrounding these regulations could have been avoided if HCFA had complied with the Regulatory Flexibility Act — by analyzing the rules' impact on small entities and soliciting public comments before publishing them. HCFA's failure to do so means the new rules will force small home health care providers to reduce services and sometimes close their doors to their neediest clients.

The Balanced Budget Act of 1997, passed in Aug. 1997, required HCFA to develop new regulations to reduce fraud in the home health care industry. However, HCFA implemented rules that require the posting of large surety bonds and capitalization for these small facilities, and impose a new limited reimbursement payment scheme. (See box on page 6.) As Chief Counsel Glover emphasized to the Senate committee, HCFA

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State Programs Highlighted

Kentucky Gov. Paul E. Patton (R) is joined by Kentucky Secretary of Economic Development Marvin E. Strong, Jr., (L) and SBA Regional Advocate Paulette Norvel-Lewis (center) at the 26th annual meeting of the Southern Growth Policies Board this past June in Louisville. For information on Kentucky's new investment fund, see story on page 5.

Regulatory Agencies

Small Manufacturers Benefit from Revised FDA Rule

Small manufacturers of antibody reagents have been spared the increased costs associated with a proposed rule by the Food and Drug Administration (FDA) to classify one of their products. On June 3, 1998, the FDA changed the final rule for immunohistochemistry reagents (IHCs) and followed alternatives offered by the Office of Advocacy. The revised final rule accomplishes the FDA's objective of protecting the public health while reducing the regulatory burden on small manufacturers.

"The FDA's reconsideration of its position demonstrates that the Office of Advocacy's efforts to minimize the cost of regulation can effectively ensure that the interests of small businesses are addressed," said the SBA's Chief Counsel for Advocacy Jere W. Glover.

IHC reagents are essentially blood derivatives manufactured for the purpose of aiding in the diagnosis of disease. Some IHCs also may be used in basic laboratory research. The FDA proposed the reclassification of the reagents on June 14, 1996, in response to industry complaints of inconsistent regulation of them. However, the proposed rule went beyond simplification of regulation and would have had a significant detrimental impact on small manufacturers who make and sell IHCs by regulating "grandfathered" products and uniformly regulating reagents that have different purposes (see story in the October 1996 issue of *The Small Business Advocate*).

Addressing these concerns, Chief Counsel Glover and Assistant Chief Counsel Shawne McGibbon submitted a comment letter to the FDA on September 3, 1996, in which they argued that the proposed rule contained the following deficiencies:

• Subjecting commercial distribution of grandfathered products to new and expensive labeling guidelines inconsistent with the FDA's own rules;

• Lumping research IHCs with clinical diagnostic IHCs into the "Class III" category (the most stringently regulated category), which would have eliminated useful research tools and hampered future research developments with costly new procedures; and

• Imposing extensive pre-market approval procedures on manufacturers of reagents in the low-risk, Class I category.

After suggesting several alternatives to the proposed FDA rule, the Office of Advocacy was pleased that the FDA responded by publishing a rule that would minimize the significant negative impact on small manufacturers of IHCs, and still accomplish the FDA's objective of protecting the public. Some of the significant changes were:

• Most IHCs will be classified as low risk, Class I devices and be exempted from time-consuming and expensive pre-market notification requirements.

• The definition of Class II IHC was broadened and the definition of Class III narrowed, so that manufacturers of most IHCs will not be required to submit new extensive scientific evidence to support the use of their products.

The FDA clarified that the final rule regulates only IHCs used for diagnostic purposes. Manufacturers of IHCs used for research purposes only will not be required to make any type of pre-market approval submissions.

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New Report Looks at Small Business Formation and Growth

From 1990 to 1995, small employer firms (those with fewer than 500 employees) accounted for 90.1 percent of net new establishments, and 76.5 percent of net new jobs, according to a newly released study by the Office of Advocacy, *Small Business Growth by Major Industry, 1988–1995*. During this same time period, according to the report, the service sector alone was responsible for 58.9 percent of net new establishments, and 84.8 percent of net new jobs.

The report, based on data collected by the Census Bureau, takes a look at the continuing cycle of business creation, growth, and death that is vital to the U.S. economy.

In announcing the release of the report, the SBA's Chief Counsel for Advocacy Jere W. Glover noted that it "shows clearly the role played by small firms in the 1988–1995 time period as they were created, as they died off, or as they grew into large firms. This so-called 'churning' is at the heart of the cycle of change that is continually reallocating the nation's financial, human, and material resources. Small business, it should come as no surprise, is at the vital center of this process."

Other findings of the report include:

• Within the services sector, the business services and health services industries seemed to be among the most active: they represented 49.0 percent of service-sector employment in 1990, but accounted for 63.8 percent of the net new jobs in the services sector from 1990 to 1995.

• Of U.S. employment, 13.3 percent in 1995 was in firms that did not exist before 1990, while 12.6 percent in 1990 was in firms that had ceased to exist by 1995.

The continuing cycle of business creation, growth, and death (and small business' vital role in the process) is the subject of a newly issued report from the Office of Advocacy.

• From 1990 to 1995, the difference between jobs generated by firm births and those lost to firm deaths accounted for 21.8 percent of net new jobs. Expansions less contractions of continuing firms accounted for 78.2 percent of these net new jobs. Small firms accounted for 67.7 percent of net new jobs from firm births and deaths, and 78.9 percent of net new jobs from continuing firms.

• In 1995, small firms averaged about one establishment and 10 employees each, while large firms had an average of more than 50 establishments and more than 3,000 employees each.

• Small businesses represented a steady share of the number of firms from 1988 to 1995, while their share of employment declined slightly. This led to an increase in average firm size.

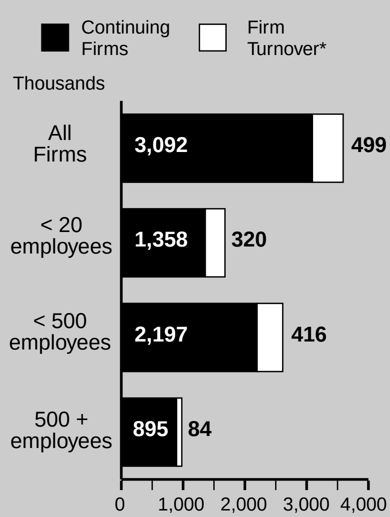
• Much of the decrease in small firms' static share of employment in the services sector was probably caused by some small firms growing into large firms and acquisitions of small firms by large firms.

• Small businesses became more important employers in the manufacturing and construction sectors and less important in the retail trade and service sectors.

Year-to-year data covering the entire time period are also included in the report.

Growing Up

Employment change from continuing firms and firm turnover, 1994–1995.



* "Firm turnover" = new jobs created by new firms, less job losses due to firm deaths.

Source: SBA, Office of Advocacy.

How to Get the Report

Copies of *Small Business Growth by Major Industry, 1988–1995* are available for purchase on paper or microfiche from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161; tel. (703) 605-6000 or through the NTIS Web site at *http://www.ntis.gov*. Ask for document no. PB98-149784. The full text of the report is also available on the Office of Advocacy's Web site at *http://www.sba.gov/ADVO/stats/#Firm*.

Conference Agenda Shapes Up; Regional Advocates Ready to Answer Your Questions

State government officials and small business leaders will come together Dec. 9–10, 1998, in Washington, D.C., to examine proven initiatives that make entrepreneurship thrive. “Vision 2000: The States and Small Business Conference,” sponsored by the SBA’s Office of Advocacy, is a conference designed to focus on business development and regulatory initiatives that work.

Look at the box to the right for a preview of the conference agenda. For more information about the conference, to nominate a state program for an award, or to register, visit the conference Web site at *http://www.sba.gov/ADVO/vision.html*, or contact Barbara George, the conference coordinator, at (202) 205-6934 or via e-mail at *barbara.george@sba.gov*.

The Conference Agenda

Preliminary agenda for the “Vision 2000” conference.

Wednesday, December 9

Morning

- Panel 1: The Importance of Small Business in the States
- Panel 2: Innovations for Capital Development Success

Afternoon

- Programs that Champion Women- and Minority-Owned Businesses
- Reaching the Rural Business
- A Booming Market for Micro-Enterprise Programs
- 1995 White House Conference Delegates: Bringing the Small Business Agenda to the States

Thursday, December 10

Morning

- Remarks by Jere W. Glover, chief counsel for advocacy, U.S. Small Business Administration
- Panel 3: Benefits of a State Small Business Conference
- Panel 4: Policies and Programs that Reduce Regulatory Burdens
- “Models of Excellence” Awards Ceremony

The SBA’s regional advocates — the Office of Advocacy’s network of field representatives — are the main point of contact for information about the Vision 2000 conference. They are available to provide agenda updates, registration forms, and information on how to nominate a program for one of the “Models of Excellence” awards.

For more information, contact the regional advocate for your state at one of the following numbers:

Region I — Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont: Ms. Elaine Guiney, tel. (617) 565-8415.

Region II — New Jersey, New York, Puerto Rico, Virgin Islands: Mr. Michael Carbone, tel. (212) 264-7750.

Region III — Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia: Mr. Joseph Sobota, tel. (215) 580-2805.

Region IV — Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee: Ms. Paulette Norvel-Lewis, tel. (404) 347-3081.

Region V — Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin: Mr. Marcus Gray, tel. (312) 353-6070.

Region VI — Arkansas, Louisiana, New Mexico, Oklahoma, Texas: Mr. Jim Johnson, tel. (817) 885-6579; Mr. Till Phillips (rural advocate), tel. (817) 885-6582.

Region VII — Iowa, Kansas, Missouri, Nebraska: Mr. Samuel Myers, tel. (816) 374-6380.

Region VIII — Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming: Ms. Joan Coplan, tel. (303) 844-0503.

Region IX — Arizona, California, Guam, Hawaii, Nevada: Position vacant. For these states, contact David Voight at (202) 205-6531.

Region X — Alaska, Idaho, Oregon, Washington: Mr. Andrew Munro, tel. (206) 553-5231.

Models of Excellence in State Programs

*The following stories are part of a continuing series in The Small Business Advocate to highlight state programs that are "Models of Excellence." State programs that are successfully advancing the growth of small business will be showcased at **Vision 2000: The States and Small Business Conference** to be held Dec. 9–10, 1998. To nominate a program or initiative for one of the "Models of Excellence" awards to be given at the conference, see the brochure attached to this issue of The Small Business Advocate.*

The Kentucky Investment Fund . . .

Investors in Kentucky may have a greater incentive to invest in small businesses thanks to new legislation passed by the Kentucky General Assembly this year. The Kentucky Investment Fund Act encourages capital investment in the development of small businesses through tax credits.

The act establishes a new program to certify privately operated venture capital funds where investors will be entitled to tax credits equal to 40 percent of their capital contributions to the fund. Investors will recover a maximum of 25 percent of their tax credit in any one year. The criteria for certification include a business plan evaluation, investment strategy analysis, and past experience of the fund manager.

SBA Regional Advocate Paulette Norvel-Lewis applauded the Kentucky legislature and said the act "exemplifies Kentucky's awareness that the promotion of small business development not only benefits the state's business community, but the nation's economy as well."

The certified venture capital funds are required to make certain investments in the development of small businesses. To qualify as a small business under the act, the entity must have more than 50 percent of its assets, operations, and employees located in Kentucky; a net worth of less than $3 million; and 100 or fewer employees.

Kentucky Governor Paul E. Patton supports the new legislation and contributed to its development. The strategic plan for the venture capital investment fund was first developed while Patton served simultaneously as lieutenant governor of Kentucky and secretary of the Economic Development Cabinet in the early 1990s.

The act became effective July 15, 1998, and certification of investment funds, cash contributions, and investment fund managers will commence on or after July 1, 1999.

. . . and The Rural Center in North Carolina

"Small business is the backbone of rural North Carolina, and it is important to support small business creation and sustainability" according to Carolyn K. Perry, director of the micro-enterprise loan program, at The Rural Center in Raleigh, N.C.

Started in 1989 with funding from the North Carolina General Assembly, the Ford Foundation, and federal entities, the microenterprise loan program is helping over a hundred businesses a year in 85 counties. The program provides loans, up to $25,000, in combination with business planning for start-up businesses and growing small companies. The program has loaned nearly $3.5 million. A recent study of self-employment issued by the University of North Carolina–Chapel Hill estimated that the current borrowers alone would add more than $6 million to the state's economy by 1999.

"The program provides access to capital to individuals in rural areas who did not have an opportunity before," Perry said. Minorities and women make up a large share of the loan recipients. One-third of borrowers are below the federal poverty level. Funding from the U.S. Small Business Administration helps support the center's small business technical assistance efforts.

"The North Carolina program is the type of endeavor that we will highlight at the Vision 2000 conference in December," said Paulette Norvel-Lewis, regional advocate for the SBA's Southeastern region, "If successful programs can be replicated throughout the United States, small businesses will thrive, and our communities will be better for it."

For more information about The Rural Center's programs, contact the center at (919) 250-4314 or by mail at 4021 Carya Drive, Raleigh, NC 27610.

HCFA, *from page 1*

was still responsible under the Regulatory Flexibility Act (RFA) to consider the economic impact of the new regulations on small entities and consider regulatory alternatives in a public rulemaking process. However, for both rulemakings the agency failed to provide a regulatory flexibility analysis of the significant burdens these regulations would impose on the small businesses that supply home health care.

Congressional critics echoed concerns raised by the industry and Chief Counsel Glover during the hearing. "Measures that were designed to weed out fly-by-night [home health care providers] with a simple $50,000 surety bond, and to reduce Medicare costs by way of a tougher reimbursement formula have given life to seriously flawed regulations that have closed down health care providers and reduced care," said Sen. John Kerry (D-Mass.).

Sen. Christopher Bond (R-Mo.), chairman of the committee, acknowledged that regulations were important to root out fraud and abuse in the Medicare and Medicaid programs, but said that the rules as implemented were driving scrupulous, quality providers out of business. "To date, about 30 home health care providers in Missouri have closed their doors — raising serious questions about access to care."

According to Glover, "The Office of Advocacy would have preferred to work early with HCFA on the regulations at issue here, not only to identify small businesses and trade associations with which HCFA should have consulted, but also to provide statistical data on the composition of the industry, using Advocacy's business data base."

A number of developments subsequent to the chief counsel's testimony make a reconsideration of HCFA's regulatory actions likely. A Senate Joint Resolution introduced by Sen. Bond that would have struck down HCFA's surety rulemaking entirely garnered 50 cosponsors. Under pressure from Congress, HCFA agreed to suspend the deadline by which home health care agencies were to have complied with the bonding requirement and to revisit the rulemaking. At the same time, several organizations have filed suit against HCFA for its failure to comply with the Regulatory Flexibility Act in both rulemakings. Finally, work is also under way to review the legislation that called for a new payment formula in the first place and to try to redirect HCFA in its implementation of this mandate.

About Bonds, Capitalization, and the Interim Payment System

The HCFA rule requiring surety bonds and high capitalization was published in final form (without any earlier opportunity for public comment) in the *Federal Register* on Jan. 5 (63 FR 292), and on March 4 amended to extend the compliance deadline (63 FR 10,732). The regulations require all Medicare and Medicaid certified home health care providers to obtain a surety bond in the amount of $50,000 or 15 percent of the amount paid to the provider by Medicare, whichever is greater. In addition, new providers must demonstrate sufficient capital to start and operate a service for three months. The Office of Advocacy pointed out in its official comments to HCFA that the bond market may not be able to provide sureties to most small entities. Chief Counsel Glover reiterated this point in his testimony before the Senate, "In the case of surety bonds, the agency published a final rule that did not reflect an understanding of the economies of the bond market. Specifically, HCFA failed to recognize that bonds are unattainable for many small home health care agencies under the parameters set in the regulation. This fact would have been uncovered if the agency had complied with the Regulatory Flexibility Act, seeking input from small entities."

On March 31, HCFA finalized a rule that sets completely new payment limits on home health care providers that went into effect retroactively to payments received on Oct. 1, 1997 (63 FR 15,718). Without an opportunity to comment on the rule before it was finalized, small firms were shocked by the new formula. Lynn Hardy, administrator of Duplin Home Care and Hospice in North Carolina, said, "I operated my agency for almost nine months before I received any indication of how much reimbursement I could expect from Medicare for services my staff had already provided." Carol Burkempher, president of Great Rivers Home Health Care, Inc., of Missouri, told the Senate Small Business Committee that her company will lose $1.5 to $1.8 million in actual costs that are not paid under the new system.

For More Information

The full text of the chief counsel's testimony before the Senate Small Business Committee is available on the Internet at *http://www.sba.gov/ADVO/testimony/1998/test7-15.html*.

For more information on this issue, contact Shawne Carter McGibbon, assistant chief counsel for food, drug, and health policy, at (202) 205-6533 or by e-mail at *shawne.carter@sba.gov*.

New Tax Laws Encourage Small Business Investment

A number of changes made in the tax laws within the last year should assure that more small businesses receive a bigger slice of the capital investment pie. The Taxpayer Relief Act of 1997 (TRA 97) and the Internal Revenue Service Restructuring and Reform Act of 1998 (RRA 98) both include provisions that reduce the capital gains tax, allow investments and gains to be rolled over among small businesses without a tax penalty, and permit investment funds (as well as individuals) to take advantage of the lower tax rates.

TRA 97 lowered tax rates on capital gains to 20 percent on most investments in securities. The RRA 98 reduced the holding period required to receive this favorable capital gains treatment from 18 months to 12 months. Dividends, on the other hand, continue to be taxed at the individual tax rate, up to 39 percent for individuals in the highest tax bracket. As a result, it has now become much more attractive to make investments that appreciate in value rather than investments that pay only dividends.

The tax law provides an incentive for investments in "qualifying small businesses" by excluding 50 percent of the gain from tax. The balance is taxed at 28 percent. Thus the effective tax rate on an investor's total gain is 14 percent. Unfortunately, for those investors wealthy enough to be subject to the alternative minimum tax, 42 percent of the gain is added back as a preference item to be taxed under the alternative minimum tax.

In addition, the 1997 and 1998 laws established a special "rollover" procedure to help steer investments to qualified small businesses. Used correctly, the procedure enables an investor (or groups of investors in funds) can cut their tax bill by 30 to 60 percent or defer gains from these sales for years, while creating a diversified portfolio of high-yield growth stocks.

Equity investments in small businesses become even more attractive with some important new changes in federal tax treatment of capital gains and rollovers.

It is important to remember that under Section 1202 of the Internal Revenue Code, gains on investments in qualifying small businesses are taxed at a lower rate of 14 percent if the stock is held for five years and meets other criteria to make it a qualified stock.

Unfortunately, the long holding period (and other qualifiers) served to discourage potential investors who were concerned about a lack of flexibility in these investments. The new laws let an investor opt out of a qualifying investment after six months; the proceeds can then be rolled over, tax-free, into another qualifying small business within 60 days. The gain in value is not taxed until the replacement stock is sold; the gain is then taxed at 14 percent. The five-year holding period still applies, but the holding period is cumulative.

An aggressive investor can build a strong portfolio with pre-tax earnings by picking good stocks and continually reinvesting the gains in small businesses. One provision of the RRA 98 clarifies that groups of investors — such as venture capital funds, partnerships, or mutual funds — can make use of the rollover provisions for the benefit of their participants.

Legislation is pending before Congress that would further alter the capital gains rate. One issue to watch is whether any changes will reduce the differential between small business and other investment rates. The incentive to invest in small and more risky businesses may be eroded if the capital gains tax rates are equalized.

For more information on this issue, contact Russell Orban, assistant chief counsel in the Office of Advocacy, at (202) 205-6533, or by e-mail at *russell.orban@sba.gov*.

Information for this article was provided, in part, from materials prepared for the American Institute of Certified Public Accountants by Russell Orban of the SBA's Office of Advocacy and Jill Gansler of Regional Management, Inc.

Electronic Payment for Federal Contractors Soon to Be a Reality

"The check is in the mail," is a phrase that may be abandoned by the federal government after it completes its transition to electronic funds transfer (EFT). Provisions of the Debt Collection Improvement Act of 1996 require that the majority of federal payments be made by EFT, rather than by check, by January 1, 1999. These payments include corporate payments to companies providing goods or services to the federal government. Regardless of the size of the company or the services provided, small businesses that are federal government contractors will need to make new arrangements through their financial institutions and contact each federal agency with which they do business.

Using the Automated Clearing House (ACH) system, financial institutions, governments, companies, and consumers will be able to transmit and receive electronic payments. To receive electronic payments through the ACH, vendors will be required to enroll with each federal agency with which they do business, by completing the "Vendor/Miscellaneous Payment Enrollment" form (SF 3881). Contractors will be required to provide the federal agency with their financial institution's banking information so that funds can be deposited electronically to the vendor's account.

(Defense Department contractors are covered under a different system. Businesses under contract to the Department of Defense (DoD) need only enroll once in DoD's Central Contractor Registry. This registration will cover all DoD payments.)

The Department of the Treasury's Financial Management Service is working to address concerns regarding vendor payments and has just completed a series of vendor payment workshops for federal agencies. Vendors have expressed a need to receive remittance information from their financial institutions, so that they can better identify, and account for, government EFT payments. Financial institutions will be required to provide the remittance information to their customers by Sept. 18, 1998. In addition, the Federal Reserve is developing an electronic data interchange (EDI) translation software for all Fedline users. The capability is expected to be ready by late 1998.

This information was provided by the Department of the Treasury's Financial Management Service (FMS). The FMS is the primary disbursing agency for the federal government, distributing about 85 percent of government payments (the Defense Department issues the bulk of the remaining payments). Currently the FMS disburses 39 percent of vendor payments electronically.

For More Information

The Financial Management Service administers the EFT system, and information for contractors can be found on the FMS home page at *http://arfc.fms.treas.gov*.

Several other government agencies have also developed alternative methods to deliver remittance information by way of their home pages, touch-tone telephone response systems, and fax-on-demand systems. Contractors can access current information about EFT on the FMS home page at *http://www.fms.treas.gov/eft* or by calling (202) 874-6670.